K113227

DEC - 8 2011

5. 510(k) SUMMARY

October 20, 2011

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Nanette Hedden
Senior Manager, Regulatory Affairs
25212 W. Illinois Route 120
Round Lake, IL 60073
Telephone: (847) 270-4871
Fax: (847) 785-5116

DEVICE NAME: Intravenous administration extension set

Trade name: Non-DEHP MICRO-VOLUME Extension Set with 0.22 Micron Filter

Table 5-1.
Product Codes for Non-DEHP MICRO-VOLUME Extension Set

Code number	Name
2N3347	Non-DEHP MICRO-VOLUME Extension Set, 36"
2N3350	Non-DEHP MICRO-VOLUME Extension Set, 60"

Common name: Extension sets with a 0.22 micron Air Eliminating Filter

Classification name: Intravascular Administration Set (21 CFR 880.5440, FPB)

PREDICATE DEVICE:

Table 5-2.
Previous 510(k)

Device	Company	Previous 510(k)	Clearance Date
Auto Syringe MICRO-VOLUME Extension Set with Air Venting Filter	Baxter Healthcare	K860746	April 7, 1986

DESCRIPTION OF THE DEVICE:

The MICRO-VOLUME Extension Set product line consists of sterile, single use disposable devices indicated for the administration of fluid to a patient's vascular system and for the removal of air and particulate matter. These intravascular administration sets provide a clinician the ability to increase the distance between the patient and the fluid administration source. The overall set configuration consists of a female Luer connector, non-DEHP microbore tubing, a 0.22 micron hydrophilic filter, and a male Luer lock connector at the distal end of the set. The filter housing also contains a 0.1 micron hydrophobic filter which vents air to the atmosphere. The MICRO-VOLUME Extension Set with a 0.22 micron filter is designed to remove air and particulate matter and has a maximum pressure of 45 psi (2241 kPa). The product is sterile and non-pyrogenic.

STATEMENT OF INTENDED USE:

The I.V. extension set with a 0.22 micron air venting filter is indicated for the administration of fluid to a patient's vascular system and for the removal of air and particulate matter.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed MICRO-VOLUME Extension Sets with a 0.22 micron filter are equivalent to Baxter's current legally marketed extension sets cleared April 7, 1986 (K860746). See Table 5-2. The MICRO-VOLUME Extension Set with a 0.22 micron filter is designed to remove air and particulate matter and has a maximum pressure of 45 psi (2241 kPa). The filter housing also contains a 0.1 micron hydrophobic filter which vents air to the atmosphere. The product is sterile and non-pyrogenic. The intended use, the basic design, function and the materials for the proposed device are equivalent to the predicate device.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet the acceptance criteria, and support that the devices are appropriately designed for their intended use. The following tests were conducted to evaluate the effect of the design modification on the functional performance of the change to the male Luer component of the MICRO-VOLUME Extension Sets:

- Bond Strength tests
- Bond Pressure tests
- ISO Luer Tests
- Biocompatibility

CONCLUSION:

The MICRO-VOLUME Extension Sets are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Baxter Healthcare Corporation
C/O Ms. Nanette Hedden
Senior Manager, Regulatory Affairs
25212 W. Illinois Route 120
Round Lake, Illinois 60073

DEC - 8 2011

Re: K113227
Trade/Device Name: MICRO-VOLUME Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Filter, Infusion Line
Regulatory Class: Class II
Product Code: FPB
Dated: October 28, 2011
Received: November 8, 2011

Dear Ms. Hedden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: MICRO-VOLUME Extension Set

Indications for Use:

The I.V. extension set with a 0.22 micron air venting filter is indicated for the administration of fluid to a patient's vascular system and for the removal of air and particulate matter.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

12/8/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113227
